REMARKS

By this Reply, claims 26-29, 31, 35, 38-40, 42-45, 47, 51, 54, 55, 73-76, 78, 82-85, 87-90, 92, 96-101, and 103 have been amended, claims 105-110 have been added, and claims 1-25, 41, 56-72, and 86 have been canceled. Accordingly, claims 26-40, 42-55, 73-85, and 87-110 are pending in this application. No new matter has been added by this Reply.

In the Office Action mailed November 5, 2007, claims 25-55 and 72-104 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,640,977 to Leahy et al. ("Leahy"), and claims 25-55 and 72-104 were rejected under 35 U.S.C. § 102(g), over the sole lost count of Patent Interference No. 104,195, based on interference estoppel.

I. The Personal Interview

Initially, Applicant would like to thank both the Examiner and Special Programs Examiner Jessica Harrison, for conducting the personal interview with Applicant's representatives, Roland G. McAndrews and Thomas Y. Ho, and inventor Frank Bonadio, on April 15, 2008. The discussion that follows is consistent with comments made during the interview. Also, the amended claim set in this Reply clarifies the structural relationship between Applicant's distal ring, diaphragm, and controlled pressurized environment, in accordance with the Examiner's suggestions in the Interview Summary mailed April 29, 2008.

According to the Interview Summary, any estoppel issues raised in the Office Action are rendered moot upon a showing of the non-obviousness of the pending claims over Leahy. Thus, because the non-obviousness of the amended claim set is the

linchpin to overcoming both the prior art rejection under 35 U.S.C.§ 102(e), and the estoppel-based rejection under 35 U.S.C. § 102(g), the following remarks begin with a discussion of non-obviousness.

II. Non-Obviousness

A. The Leahy Reference

Leahy discloses a surgical apparatus 10 for permitting hand-assisted laparoscopic surgery. Referring to FIGS. 3 and 4 of Leahy, the apparatus 10 includes an outer sleeve 18 having an axial entry opening 23a and a lateral exit opening 24, exit opening 24 being located adjacent an incision in a patient. A first sealing means is provided for sealing the exit opening 24, and a second sealing means is provided for sealing the entry opening 23a, creating a sealed chamber C in sleeve 18 that prevents gas from escaping from an insufflated abdominal cavity A. The first sealing means includes an adhesive on a lower exposed flange 26 of the apparatus, the adhesive being adhered directly to the patient's body or to the body by way of a drape D that is adhered to the body. See Leahy, column 3, lines 60-67; column 5, lines 14, 15, and 31-34; and column 7, lines 36-43. The second sealing means may include, for example, an inflatable cuff 20 located at the entry opening 23a. See Id. at column 3, lines 49-54. In addition, Leahy discloses a wound protector 12 separate from the surgical apparatus 10 comprising a thin flexible tube 13 for engaging a wound W in an abdominal wall L of the patient, and flexible O-rings 14 and 16 located at opposite ends of tube 13. See Id. at column 2, lines 9 and 10; and column 4, lines 1-10.

B. New Independent Claims 105 and 108

New independent claim 105 recites, *inter alia*, "an entry seal assembly located proximal the tubular diaphragm and configured to maintain a controlled pressurized environment inside the surgical device, the engagement of the incision engaging portion to the incision and the distal ring to the internal body tissue forming a primary coupling of the surgical device to the patient." New independent claim 108 recites, *inter alia*, "creating a controlled pressurized environment inside the surgical device; and forming a primary coupling of the surgical device to the patient through an engagement of the diaphragm and distal ring with the incision and internal body tissue." Support for the recited features in both new independent claims can be found on page 9, line 27, through page 10, line 4 of Applicant's specification, and FIG. 9 of Applicant's drawings.

Leahy does not teach that O-ring 14 and tube 13 form a primary coupling of surgical apparatus 10 to the patient. Moreover, even if O-ring 14 and tube 13 could somehow be interpreted as forming a coupling of surgical apparatus 10 to the patient, and Applicant does not agree that it can, such a coupling would be secondary to the coupling provided by flange 26 and adhesive 28, which adheres surgical apparatus 10 to the patient. See Id. at column 3, lines 15-19.

The primary coupling set forth in new independent claims 105 and 108 provides numerous advantages that are not disclosed or recognized in Leahy. As illustrated in FIG. 9 and explained at page 9, line 27, through page 10, line 4, of the present application, the engagement of a tubular diaphragm 62 and a distal ring 63 to an incision and body tissue 30, forms a primary coupling of a surgical device 60 to the patient. By using tubular diaphragm 62 and distal ring 63 to form the primary coupling,

surgical device 60 does not require the use of an adhesive to maintain coupling of surgical device 60 to the patient during a surgical procedure. This avoids drawbacks associated with adhesive couplings. For example, adhesive couplings are susceptible to separation from the patient resulting in a loss of insufflation pressure from inside the patient. In addition, adhesive couplings do not utilize the insufflation pressure to assist in coupling the device to the patient. Rather, such adhesive couplings work against the insufflation pressure by tending to separate or detach at increased pressures.

In addition, forming the primary coupling using tubular diaphragm 62 and distal ring 63 avoids problems associated with varying thicknesses of patients' skin. The anchoring of surgical device 60 by distal ring 63 located within the incision may allow tubular diaphragm 62 to be stretched or tensioned to extend through many different skin thicknesses.

In contrast, a device that relies on an adhesive coupling to secure the device to a patient outside the body would not necessarily stretch or tension the material extending out from inside the body, and thus would require appropriate sizing to match the thickness of the patient's skin to assure that a distal end of the material does not dangle within the patients body. Accordingly, devices that utilize adhesives to couple the device to a patient outside the body would need to be separately sized for the many different skin thicknesses of patients to avoid excess material from extending into the body. This drawback is present in Leahy. See Leahy at column 4, lines 48-59. For at least the above reasons, new independent claims 105 and 108 are novel and non-obvious over Leahy.

C. New Independent Claim 106

New independent claim 106 recites, *inter alia*, "an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment." Support for the features recited in new independent claim 106 can be found on page 9, line 27, through page 10, line 4 of Applicant's specification, and FIG. 9 of Applicant's drawings.

Leahy does not teach that increasing the pressure in chamber C will increase engagement of distal ring 14 and tube 13 with abdominal wall L and wound W. This is due to the coupling of surgical apparatus 10 of Leahy to the top of abdominal wall L using flange 26 and adhesive 28. As long as flange 26 is adhered to the top of abdominal wall L, increasing pressure in chamber C will not urge tube 13 and ring 14 relative to wound W and abdominal wall L to increase their engagement with wound W and abdominal wall L. Thus, adhesive couplings, like those in Leahy, fail to utilize the insufflation pressure to assist in coupling the device to the patient. Rather, such adhesive couplings work against the insufflation pressure by tending to separate or detach at increased pressures.

The increase in engagement with increasing pressure, described in new independent claim 106, provides numerous advantages that are not disclosed or recognized in Leahy. For example, in the present application, increasing the engagement of tubular diaphragm 62 and distal ring 63 with the incision and body tissue 30 using an increase in pressure allows coupling of surgical device 60 to the

patient without requiring the use of adhesive. Other advantages have been discussed above with respect to new independent claims 105 and 108. For at least the above reasons, new independent claim 106 is novel and non-obvious over Leahy.

D. New Independent Claim 107

New independent claim 107 recites, *inter alia*, "the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment." Support for the recited features can be found on page 9, line 27, through page 10, line 4 of Applicant's specification, and FIG. 9 of Applicant's drawings.

Leahy discloses that flange 26 and adhesive 28 form the first sealing means. This suggests that flange 26 of Leahy acts as like a boundary structure having a first side (below flange 26 in FIG. 3) subject to the same pressure as the pressurized gas in cavity A, and a second side (above flange 26 and outside of sleeve 18 in FIG. 3) subject to atmospheric pressure. Since both the wound engaging portion of tube 13 and the internal portion of tube 13 are on the first side of the boundary (below flange 26 in FIG. 3), they are both subject to the pressure associated with the pressurized gas in cavity A.

Applicant's claimed arrangement of having the internal portion of tubular diaphragm 62 subject to the controlled pressurized environment, while having the wound engaging portion of tubular diaphragm 62 not subject to the controlled pressurized environment, provides numerous advantages that are not disclosed or recognized in Leahy. The arrangement allows distal ring 63 and diaphragm 62 to

together form the only coupling with the patient's body. As such, the use of an adhesive to maintain coupling to the patient is entirely avoided, along with the drawbacks associated with using adhesive (discussed above with respect to independent claims 105 and 108). Additionally, the arrangement provides advantages in terms of coupling and ability to adapt to different skin thicknesses (also discussed above with respect to independent claims 105 and 108). For at least the above reasons, new independent claim 107 is novel and non-obvious over Leahy.

Since new independent claims 105-108 are novel and non-obvious over Leahy, and because the showing of non-obviousness serves to overcome both the prior art rejection under 35 U.S.C. § 102(e), as well as the estoppel-based rejection under 35 U.S.C. § 102(g) (see the Interview Summary), Applicant submits that new independent claims 105-108 are allowable. In addition, Applicant hereby incorporates the arguments for patentability presented in the Reply to Office Action dated January 5, 2006 in support of the allowability of the pending claims.

E. Dependent Claims

Applicant submits that the claims depending either directly or indirectly from new independent claims 105-108 are novel, non-obvious, and allowable for at least the same reasons that new independent claims 105-108 are novel, non-obvious, and allowable. In addition, the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore are also separately patentable.

III. Benefit Under 35 U.S.C. § 119(d)

Applicant's claims are entitled to the priority date of at least Irish Patent Application No. 930649 ("the '649 application"), filed September 6, 1993, under 35 U.S.C. § 119(d) for at least the reasons discussed in the Reply to Office Action filed January 5, 2006. Further, contrary to page 3 of the Office Action, the Board of Patent Appeals and Interferences ("BPAI") has not held that as a matter of law, Applicant is not entitled to the priority date of the '649 application. First, to the extent that the withholding of the priority date is based on estoppel, Applicant's showing of non-obviousness over Leahy renders that basis moot (per the Interview Summary). Second, case law, and in particular, In re Deckler, 977 F.2d 1449 (Fed. Cir. 1992), does not support the withholding of the priority date of the '649 application from Applicant. The sole issue in Deckler was whether the losing party in an interference proceeding is entitled to a patent covering claims the party admits are patentably indistinguishable from the claim involved in the interference. See Id. at 1450. Applicant, however, is seeking claims that are patentably distinguishable from the claim involved in the interference. Thus, Deckler is inapplicable to the present case. Moreover, Deckler deals with preclusion as to claims, and is silent as to preclusion as to priority under 35 U.S.C. § 119(d).

Furthermore, the BPAI's denial of Applicant's right to the priority date under 35 U.S.C. § 119(d) came in the form of a decision on a preliminary motion. A decision on a preliminary motion in an interference proceeding is not a final judgment for res judicata or estoppel purposes. See Curtis Mfg. Co., Inc. v. Plasti-Clip Corp., 933 F. Supp. 94, 103 (D.N.H. 1995). For this additional reason, Applicant is not barred

from seeking benefit of the priority date of the '649 application, and is entitled to the priority date for at least the reasons discussed in the Reply to Office Action mailed January 5, 2006.

IV. Conclusion

Should the Examiner believe that a discussion of this application would expedite resolution of outstanding matters, the Examiner is invited to call the undersigned at 202.408.4420.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action. Further, in discussing the specification, claims, and drawings in this Reply, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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Thomas Ho

Dated: May 5, 2008

By:_____
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